

- **Wash the application site(s) thoroughly** with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated
- In the event that unwashed or unclothed skin to which testosterone gel has been applied comes in contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible.

17.3 Potential Adverse Reactions with Androgens

Patients should be informed that treatment with androgens may lead to adverse reactions which include:

- Changes in urinary habits such as increased urination at night, trouble starting your urine stream, passing urine many times during the day, having an urge that you have to go to the bathroom right away, having a urine accident, being unable to pass urine and weak urine flow.
- Breathing disturbances, including those associated with sleep, or excessive daytime sleepiness.
- Too frequent or persistent erections of the penis.
- Nausea, vomiting, changes in skin color, or ankle swelling.

17.4 Patients Should Be Advised:

- **To read the Medication Guide before starting AndroGel therapy and to reread it each time the prescription is renewed**
- **Of the appropriate application and use of AndroGel to maximize the benefits and to minimize the risk of secondary exposure in children and women**
- To keep AndroGel out of the reach of children
- **That AndroGel is an alcohol based product and is flammable; therefore avoid fire, flame or smoking until the gel has dried**
- Of the importance of adhering to all recommended monitoring
- To report any changes in their state of health, such as changes in urinary habits, breathing, sleep, and mood
- To wait 5 hours before showering or swimming. This will ensure that the greatest amount of AndroGel is absorbed into their system.

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Abbott Laboratories
North Chicago, IL 60064, U.S.A.

U.S. Patent No. 6,503,894

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500122/500127 4E Rev March 2011



17.5 FDA-Approved Medication Guide

MEDICATION GUIDE

AndroGel® (AN DROW JEL) CIII (testosterone gel) 1%

Read the Medication Guide that comes with AndroGel before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about AndroGel?

Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through contact with men using AndroGel.

AndroGel can transfer from your body to others. This can happen if other people come into contact with the area where the AndroGel was applied to your skin.

- Women and children should avoid contact with the unwashed or unclothed area where AndroGel has been applied.
- To lower the risk of transfer of AndroGel from your body to others, you should follow these important instructions:
 - Apply AndroGel **only** to areas that will be covered by a short sleeve T-shirt. These areas are your shoulders and upper arms, or stomach area (abdomen), or shoulders, upper arms and stomach area.
 - Wash your hands **right away** with soap and water after applying AndroGel.
 - After the gel has dried, **cover the application area with clothing**. Keep the area covered until you have washed the application area well or have showered.
 - **If you expect to have skin-to-skin contact with another person, first wash the application area well with soap and water.**
 - **If a woman or child makes contact with the AndroGel application area, that area on the woman or child should be washed well with soap and water right away.**

Stop using AndroGel and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to AndroGel:

Signs and symptoms in **children** may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms in **women** may include:

- changes in body hair
- a large increase in acne

What is AndroGel?

AndroGel is a prescription medicine that contains testosterone. AndroGel is used to treat adult males who have low or no testosterone.

It is not known if AndroGel is safe or effective in children younger than 18 years old. Improper use of AndroGel may affect bone growth in children.

AndroGel is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your AndroGel in a safe place to protect it. Never give your AndroGel to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

AndroGel is not meant for use in women.

Who should not use AndroGel?

Do not use AndroGel if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or breast-feeding. AndroGel may harm your unborn or breast-feeding baby.

Women who are pregnant or who may become pregnant should avoid contact with the area of skin where AndroGel has been applied.

- are allergic to testosterone or any of the ingredients in AndroGel including soy. See the end of this Medication Guide for a complete list of ingredients in AndroGel.

Talk to your healthcare provider before taking this medicine if you have any of the above conditions.

What should I tell my healthcare provider before using AndroGel?

Before you use AndroGel, tell your healthcare provider if you:

- have breast cancer or prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have liver or kidney problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using AndroGel with certain other medicines can affect each other.

Especially, tell your healthcare provider if you take:

- insulin
- corticosteroids
- medicines that decrease blood clotting

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use AndroGel?

- It is important that you apply AndroGel exactly as prescribed by your healthcare provider. Your healthcare provider will tell you how much AndroGel to apply and when to apply it.
- Your healthcare provider may change your AndroGel dose. Do not change your AndroGel dose without talking to your healthcare provider.
- AndroGel is for skin use only.
- **Do not allow others to apply AndroGel to your body.**
- Applying AndroGel:

AndroGel comes in a pump or in packets.

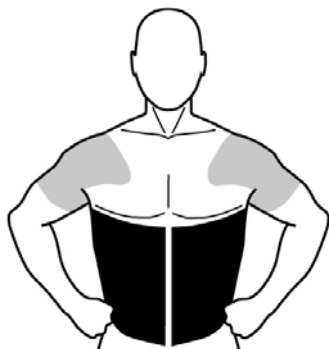
If you are using the AndroGel pump:

- Before using the pump for the first time, you will need to prime the pump. To prime AndroGel, fully push down on the pump 3 times. Do not use any AndroGel that came out while priming. Wash it down the sink or throw it in the trash to avoid accidental exposure to others. Your AndroGel pump is ready to use now.
- Your healthcare provider will tell you the number of times to press the pump for each dose.

If you are using AndroGel packets:

- Tear open the packet completely at the dotted line.
- Squeeze all of the AndroGel out of the packet into the palm of your hand. Squeeze from the bottom of the packet to the top.
- Throw away the packet in the trash out of the reach of children to avoid accidental exposure.

- Squeeze the medicine into the palm of your hand and apply to clean dry, intact skin at the same time each day.
- You may also apply AndroGel from the pump or packet directly to your skin.
- **Apply AndroGel only to areas that will be covered by a short sleeve t-shirt, as shown in the shaded areas in the figure below. These areas are your shoulders and upper arms, or stomach area, or shoulders, upper arm and stomach area.**



- **Do not apply AndroGel to your penis or scrotum.**
- **Wash your hands with soap and water right after you apply AndroGel.**
- Let the application areas dry for a few minutes before putting on a shirt.
- To prevent transfer of AndroGel to others, clothes (such as a t-shirt) should **always** be worn to cover the AndroGel application areas until you have washed the application areas well with soap and water.
- **Wait 5 hours before showering or swimming. This will ensure that the greatest amount of AndroGel is absorbed into your system.**
- **AndroGel is flammable until dry. Let the gel dry before smoking or going near an open flame.**

Your healthcare provider will test your blood before you start and while you take AndroGel.

What are the possible side effects of AndroGel?

AndroGel can cause serious side effects including:

- See “What is the most important information I should know about AndroGel?”
- **If you already have enlargement of your prostate gland your signs and symptoms can get worse while using AndroGel. This can include:**
 - increased urination at night
 - trouble starting your urine stream
 - having to pass urine many times during the day
 - having an urge that you have to go to the bathroom right away
 - having a urine accident
 - being unable to pass urine or weak urine flow
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use AndroGel.
- **In large doses AndroGel may lower your sperm count.**
- **Swelling of your ankles, feet, or body, with or without heart failure.**
- **Enlarged or painful breasts.**

- **Have problems breathing while you sleep (sleep apnea).**
- **Blood clots in the legs.** This can include pain, swelling or redness of your legs.

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of AndroGel include:

- acne
- skin irritation where AndroGel is applied
- increased cholesterol levels
- increased prostate specific antigen (a test used to screen for prostate cancer)
- increased red blood cell count
- increased liver function tests

Other side effects include more erections than are normal for you or erections that last a long time.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AndroGel. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AndroGel?

- Store AndroGel between 59°F to 86°F (15°C to 30°C).
- Safely throw away used AndroGel in household trash. Be careful to prevent accidental exposure of children or pets.
- Keep AndroGel away from fire.

Keep AndroGel and all medicines out of the reach of children.

General information about AndroGel

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AndroGel for a condition for which it was not prescribed. Do not give AndroGel to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about AndroGel. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about AndroGel that is written for health professionals.

For more information, go to www.ANDROGEL.com or call 1-800-241-1643.

What are the ingredients in AndroGel?

Active ingredient: testosterone

Inactive ingredients: carbomer 980, ethyl alcohol 67.0%, isopropyl myristate, purified water and sodium hydroxide.

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Abbott Laboratories

North Chicago, IL 60064, U.S.A.

500122/500127 3E Rev March 2011

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued March 2011



Reference ID: 2916005